OCT - 5 2000

K002777

510(K) SUMMARY

Greiner Vacuette® Tubes with PPACK

Greiner Vacuette North America, Inc.
P.O Box 1026
Monroe, NC 28111
September 5, 2000

For information regarding this 510(k) Summary, please contact Greiner Vacuette® North America, Douglas L. Harris.

Device Names:

Proprietary Name: Vacuette® with PPACK

Common Name: Blood Collection Tube with PPACK

Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection

Device Description:

The Greiner Vacuette® blood collection tube with PPACK additive is an evacuated blood collection device that is processed through centrifugation to separate blood plasma from the cellular components of blood. PPACK is a direct thrombin inhibitor. The tube is composed of clear plastic. The cap is made of plastic and rubber. The tube size is 13 x 75 mm. The tube is equipped with a vacuum tube holder to assist in positioning the product when obtaining blood samples. The vacuum tube holder is composed of plastic.

Intended Use:

Vacuette® Tubes with PPACK are used to collect, transport and separate plasma from the cellular components of blood for testing in the clinical laboratory.

Substantial Equivalence:

The Greiner Vacuette® with PPACK has been found to be substantially equivalent to the Greiner Vacuette with lithium heparin (K# 960857). Both blood collection tubes have the same intended use and contain the same tube material and stopper material. The tubes have different additives. The predicate device, Greiner Vacuette plasma tube with lithium heparin, contains lithium heparin. The Greiner Vacuette plasma tube with PPACK contains D-phenylalanyl-prolyl-arginine-chloromethylketone Dihydrochloride (PPACK).

A study was conducted on blood collected from 50 donors into each type of tube. Test results of 24 analytes commonly tested in plasma showed equivalent performance of the two anticoagulants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 5 2000

Greiner Labortechnik Gmbh.
c/o Ms. Judith J. Smith
Sienna Partners, L.L.C.
PO Box 6581
Ellicott City, Maryland 21042-0581

Re: K002777
Trade Name: Vacuette® Tubes with PPACK
Regulatory Class: II
Product Code: JKA
Dated: September 5, 2000
Received: September 6, 2000

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002777

Device Name: Vacuette® Tubes with PPACK

Indications For Use:

Vacuette® Tubes with PPACK are used to collect, transport and separate plasma from the cellular components of blood for testing in the clinical laboratory.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002777

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)